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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,187	06/15/2001	Annamaria Naggi	DI-5373 CON	8866

29200 7590 12/03/2002

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EXAMINER

YOUNG, JOSEPHINE

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/03/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/882,187

Applicant(s)

NAGGI ET AL.

Examiner

Josephine Young

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: The Markush members of claim 1 should be separated by the appropriate punctuation.

Further, claim 10 and 16 are objected to because of the absence of a period.

Appropriate correction is required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 5-22 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 5-22 of copending Application No. 09/206,063. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claims 2-4 is a relative term that renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. § 103 as being unpatentable over US 4,886,789 to MILNER in view of EP 0 612 528 A1 to BELLINI et al.

Claims 1-4 are drawn to a sterilized peritoneal dialysis solution comprising a starch containing a glucose polymer linked predominately by 1,4 bonds and selected from the group consisting of D-glucitol, gluconic acid and an alkylglycoside.

MILNER discloses the use of a glucose polymer mixture in a peritoneal dialysis composition (see abstract and col.3, line 1- line 68). MILNER also discloses that the prior art teaches the use of carbohydrate polymers having an average degree of polymerization of at least

4 in concentrations sufficient safely to effect the removal of solutes and water from a patient by peritoneal dialysis (col. 1, line 56 to col.2, line 66).

MILNER does not disclose the use of gluconic acid. Although MILNER teaches the use of starch with 1, 6 linkages, MILNER does not exclude the use of starch with 1, 4 linkages.

BELLINI teaches the advantageous use of gluconic acid and its pharmaceutically acceptable salts with glucose in a peritoneal dialysis composition to lower or reduce the negative effects such as obesity, the facilitation of hypertriglyceridemia and alterations in insulin and glucagon hormone levels, associated with high concentrations of glucose.

A prima facie case of obviousness is supported when the prior art alone would have appeared to suggest doing, at the time the invention was made, what the applicant has done. Given routine experimentation common to practice of an invention in any art, one of skill in the art would have been provided with a clear motivation and a reasonable expectation of success to use glucitol, gluconic acid and an alkylglycoside in a peritoneal dialysis solution. Expected beneficial results are evidence of obviousness just as unexpected beneficial results are evidence of non-obviousness.

A patentable compound or composition of matter is one that is produced by intermixture of two or more specific ingredients; and possesses properties pertaining to none of these ingredients separately, thereby accomplishing a new and useful result. In the instant application, the prior art teaches the use of a mixture of glucose polymers, gluconic acid and glucose derivatives in peritoneal dialysis solutions. To impart patentability to an otherwise obvious chemical composition, must produce more than a mere difference in degree in the properties of the composition. The proportions must be critical, i.e. they must produce a difference in kind

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rather than degree. As such, applicant has not shown how the composition of gluconic acid, D-glucitol and an alkylglycoside would produce an unexpected result from the prior art or would not be expected to be beneficial in a peritoneal dialysis solution.

The use of gluconic acid, D-glucitol and an alkylglycoside would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made given the use of gluconic acid and glucose polymers in general in peritoneal dialysis solutions in the prior art.

A person of ordinary skill in the art would have been motivated to use gluconic acid, D-glucitol and an alkylglycoside in light of the prior art teaching the beneficial use of a mixture of these compounds, specifically the incorporation of gluconic acid in a peritoneal dialysis solution, over glucose alone as these additives may reduce the negative metabolic effects associated with glucose alone.

Claims 5-22 are rejected under 35 U.S.C. 103 as being unpatentable over SOLOMONS, Organic Chemistry, 2nd edition, 1976, p. 890, in combination with AMAN et al., Carbohydrates in Food, p. 195, 1996 and HORN et al., U.S. Patent No. 3,974,034.

Claims 5-22 are drawn to a method of preparing a stabilized osmotic agent by treating starch with either NaBH₄ or NaOCl.

The use of sodium borohydride to reduce saccharides is well known in the art as SOLOMONS teaches that aldoses and ketoses can be reduced with sodium borohydrides and Eliasson teaches that other non-cellulosic polysaccharides (e.g. arabinoxylans, xyloglucans, and glucomannans) are preferentially extracted using aqueous solutions of alkali, containing sodium borohydride. The borohydride converts the reducing end groups of the polysaccharides to a

hydroxymethyl group, and this decreases the incidence of alkaline degradation. Although the 1,4 starch is not specifically mentioned, the selective target for reduction is the hydroxyl group for which NaBH_4 is highly selective for.

HORN teaches that the oxidation of starch leads to a starch product which is more easily solubilized and which exhibits a lower viscosity when solubilized in water and that oxidation may be carried out by utilizing any of a number of oxidizing agents which are synonymous with bleaching agents such as perborates, periodic acid, persulfates and hypochlorite (col.2, line 57 - col. 3, line 36).

The intended use of the resulting product of the processes set forth in claims 5-22 does not have patentable weight. The claims are process claims for either reducing or oxidizing a starch using NaBH_4 and NaOCl , respectively.

It would have been prima facie obvious to use NaBH_4 to reduce a starch or NaOCl to oxidize a starch.

Given that these agents have been set forth in the prior art as having a selectivity for the processes of reducing or oxidizing polyols as well as the art recognized advantage of increasing solubility and lowering viscosity (as in the case of NaOCl), one of skill in the art would have been motivated to use these agents for said processes as well as have more than a reasonable expectation of success in the use of these agents for said processes.

Conclusion

Claims 1-22 are pending. Claims 1-22 are rejected. No claims are allowed.

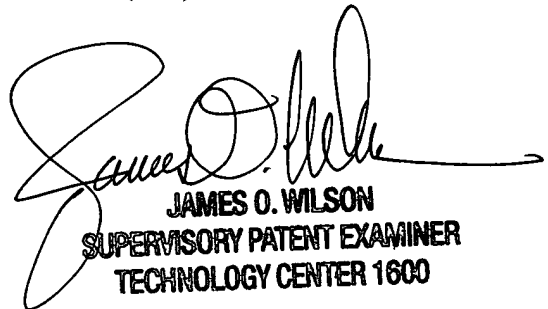
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Josephine Young whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JY
December 2, 2002



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600